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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
Brent Iverson *et al.*

Serial No.: 09/813,444

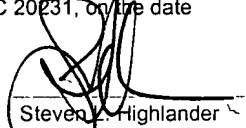
Filed: March 20, 2001

For: DIRECTED EVOLUTION OF ENZYMES  
AND ANTIBODIES

Group Art Unit: 1646

Examiner: Unknown

Atty. Dkt. No.: MXGN:005USC2/SLH

CERTIFICATE OF MAILING 37 C.F.R. 1.8	
I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231, on the date below:	
December 14, 2001	
Date	
	Steven L. Highlander

### INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
Washington, D.C. 20231

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

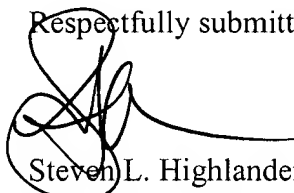
In accordance with 37 C.F.R. §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is hereby authorized to deduct said fees from Fulbright & Jaworski Deposit Account No.: 50-1212/10102540/SLH.

This application is a continuation application of Serial No. 08/847,063, filed May 1, 1997 and is relied upon for an earlier filing date under 35 U.S.C. § 120. In accordance with Rule 37 C.F.R. § 1.98(d) only copies of those documents not previously cited and submitted to the Patent and Trademark Office in prior application Serial No. 08/847,063 are enclosed for the convenience of the Examiner.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,



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Date: December 14, 2001

Form PTO-1449 (modified)		Atty. Docket No. MXGN:005USC2/SLH	Serial N . 09/813,444
List of Patents and Publications for Applicant's  INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)		Applicant Brent Iverson <i>et al.</i>	
		Filing Date: March 20, 2001	Group: 1646
U.S. Patent Documents See Page 1	Foreign Patent Documents See Page 3	Other Art See Page 3	

### U.S. Patent Documents

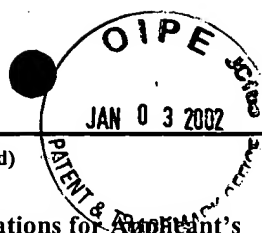
Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A1	Re. 34,606	05/10/94	Estell <i>et al.</i>			
	A2	3,791,932 ✓	2/12/74	Schuurs <i>et al.</i>	195	103.5	1/27/72
	A3	3,949,064	4/6/76	Bornstein <i>et al.</i>	424	1	10/26/73
	A4	4,034,074	07/05/77	Miles			
	A5	4,166,767	09/04/79	Kurooka <i>et al.</i>			
	A6	4,174,384	11/13/79	Ullman <i>et al.</i>	424	8	10/12/76
	A7	4,496,658	01/29/85	Kondo <i>et al.</i>			
	A8	4,596,792	6/24/86	Vyas	514	21	3/30/84
	A9	4,599,230 ✓	7/8/86	Milich <i>et al.</i>	424	89	3/9/84
	A10	4,601,903 ✓	7/22/86	Frasch	424	92	5/1/85
	A11	4,608,251 ✓	8/26/86	Mia	424	85	11/9/84
	A12	4,748,119	05/31/88	Rich <i>et al.</i>			
	A13	4,760,025	07/26/88	Estell <i>et al.</i>			
	A14	4,873,192	10/10/89	Kunkel			
	A15	4,918,162	4/90	Slamon <i>et al.</i>	530	324	
	A16	4,952,501	8/90	Jasin <i>et al.</i>	435	69.2	
	A17	4,959,312	09/25/90	Sirotkin			
	A18	5,081,030	1/92	Civin	435	240.2	
	A19	5,093,240	03/03/92	Inouye <i>et al.</i>			
	A20	5,223,409	06/29/93	Ladner <i>et al.</i>			
	A21	5,264,365 ✓	5,264,365	Georgiou <i>et al.</i>	435	252.8	11/9/90
	A22	5,348,867	09/20/94	Georgiou <i>et al.</i>			
	A23	5,403,484 ✓	4/4/95	Ladner <i>et al.</i>	435	235.1	1/26/93

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INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)



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U.S. Patent Documents See Page 1	Foreign Patent Documents See Page 3	Other Art See Page 3

**U.S. Patent Documents**

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A24	5,441,882	08/15/95	Estell <i>et al.</i>			
	A25	5,445,935 ✓	8/29/95	Royer	435	6	11/23/92
	A26	5,541,309 ✓	7/30/96	Prasher	536	23.2	10/28/94
	A27	5,550,045	8/96	Musters <i>et al.</i>	435	201	
	A28	5,599,231 ✓	2/4/97	Hibino <i>et al.</i>	463	29	10/31/94
	A29	5,605,793 ✓	2/25/97	Stemmer	435	6	2/17/94
	A30	5,672,490	9/97	Sessler <i>et al.</i>	435	91.1	
	A31	5,723,323	03/03/98	Kauffman <i>et al.</i>			
	A32	5,733,541	03/31/98	Taichman <i>et al.</i>			
	A33	5,744,302	4/98	Sessler <i>et al.</i>	435	6	
	A34	5,763,192	06/09/98	Kauffman <i>et al.</i>			
	A35	5,811,238 ✓	9/22/98	Stemmer <i>et al.</i>	435	6	11/30/95
	A36	5,830,696 ✓	11/3/98	Short	435	69.1	12/5/96
	A37	5,830,721 ✓	11/3/98	Stemmer <i>et al.</i>	435	172.1	2/17/95
	A38	5,843,701	12/98	Gold <i>et al.</i>	435	68.1	
	A39	5,866,344 ✓	2/2/99	Georgiou	435	7.21	5/23/95
	A40	5,939,250 ✓	8/17/99	Short	435	4	5/22/96
	A41	5,958,672 ✓	9/28/99	Short	435	4	6/3/96
	A42	5,965,408 ✓	10/12/99	Short	435	91.1	7/9/96
	A43	6,001,574 ✓	12/14/99	Short <i>et al.</i>	435	6	3/4/98
	A44	6,004,788 ✓	12/21/99	Short	435	183	7/18/95
	A45	6,015,561	1/00	Alvarez	424	155.1	
	A46	6,030,779 ✓	2/29/00	Short	435	6	10/6/97

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Form PTO-1449 (modified)

List of Patents and Publications for Applicant's

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March 20, 2001Group:  
1646U.S. Patent Documents  
*See Page 1*Foreign Patent Documents  
*See Page 3*Other Art  
*See Page 3*

## U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A47	6,054,267 ✓	4/25/00	Short	435	6	8/2/96
	A48	6,057,103 ✓	5/2/00	Shrot	435	6	8/26/97
	A49	6,107,059	8/00	Hart	435	69.7	
	A50	6,117,679 ✓	9/12/00	Stemmer	435	440	3/25/96
	A51	6,132,970 ✓	10/17/00	Stemmer	435	6	6/19/98
	A52	6,165,793 ✓	12/26/00	Stemmer	435	440	5/8/98
	A53	6,168,919 B1 ✓	1/2/01	Short	435	6	7/17/96
	A54	6,171,820 B1 ✓	1/9/01	Short	435	69.1	2/4/99
	A55	6,174,673 B1 ✓	1/16/01	Short <i>et al.</i>	435	6	6/16/98
	A56	6,180,406 B1 ✓	1/30/01	Stemmer	435	440	6/17/98

## Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B1	EP 0285123	10/05/88	Europe			
	B2 ✓	EP 0095361	11/30/83	Europe			
	B3 ✓	WO 94/26787 ✓	11/24/94	PCT			

## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C1 ✓	Agterberg <i>et al.</i> , "Outer-membrane PhoE protein of <i>Escherichia coli</i> K-12 as an exposure vector: possibilities and limitations," <i>Gene</i> 88:37-45, 1990
	C2 ✓	Aiyar and Leis, "Modification of the Megaprimer Method of PCR Mutagenesis: Improved Amplification of the Final Product," <i>BioTechniques</i> , 14(3):366, 1993.

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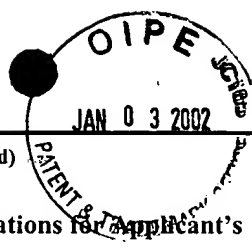
Exam. Init.	Ref. Des.	Citation
	C3	Amaravadi and King, "A rapid and efficient, nonradioactive method for screening recombinant DNA libraries," <i>BioTech.</i> , 16(1):98-103, 1994.
	C4	Baneyx and Georgiou, "In vivo degradation of secreted fusion proteins by the <i>Escherichia coli</i> outer membrane protease OmpT," <i>J. Bacteriol.</i> , 172:491-494, 1990.
	C5	Barbas and Lerner, "Combinatorial Immunoglobulin libraries on the surface of phage (Phabs): Rapid selection of antigen-specific fabs," <i>Methods: A companion to Methods in Enzymology</i> , 2(2):119-124, 1991.
	C6	Barbas III <i>et al.</i> , "Assembly of combinatorial antibody libraries on phage surfaces: The gene III site," <i>Proc. Natl. Acad. Sci. USA</i> , 88:7978-7982, September 1991.
	C7	Barbas III <i>et al.</i> , "Semisynthetic combinatorial antibody libraries: A chemical solution to the diversity problem," <i>Proc. Natl. Acad. Sci. USA</i> , 89:4457-4461, May 1992.
	C8	Barbas, "Recent advances in phage display," <i>Curr. Opin. BioTech.</i> , 4(5):526-530, 1993.
	C9	Bardwell <i>et al.</i> , "Identification of a protein required for disulfide bond formation in vivo," <i>Cell</i> , 67:581-589, 1991.
	C10	Bathurst, "Protein expression in yeast as an approach to production of recombinant malaria antigens," <i>Am. J. Trop. Med. Hyg.</i> , 50(4 Suppl):20-26, 1994.
	C11	Beher, "Correlation between the expression of an <i>Escherichia coli</i> cell surface protein and the ability of the protein to bind to lipopolysaccharide," <i>J. Bacteriol.</i> , 143(1):403-410, 1980.
	C12	Bender <i>et al.</i> , "Recombinant human antibodies: linkage of an Fab fragment from a combinatorial library to an Fc fragment for expression in mammalian cell culture," <i>Hum. Antibodies Hybridomas</i> , 4(2):74-79, 1993.
	C13	Better <i>et al.</i> , " <i>Escherichia coli</i> Secretion of an Active Chimeric Antibody Fragment," <i>Science</i> , 240:1041-1043, May 1988.
	C14	Bird <i>et al.</i> , "Single-chain antigen-binding proteins," <i>Science</i> , 242:423-426, 1988.
	C15	Blackburn <i>et al.</i> , "Electrochemiluminescence detection for development of immunoassays and DNA probe assays for clinical diagnostics," <i>Clinical Chemistry</i> , 37(9):1534-1539, 1991.
	C16	Boder and Wittrup, "Yeast surface display for screening combinatorial polypeptide libraries," <i>Nat. Biotechnol.</i> , 15(6):553-557, 1997.

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	C17	Bolivar <i>et al.</i> , "Construction and characterization of new cloning vehicles. II a multipurpose cloning system," <i>Gene</i> , 2:95-113, 1977.
	C18	Bosch <i>et al.</i> , "Periplasmic accumulation of truncated forms of outer-membrane PhoE protein of <i>Escherichia coli</i> K-12," <i>J. Mol. Biol.</i> , 189:449-455, 1986.
	C19	Bosch <i>et al.</i> , "The role of the carboxy-terminal membrane-spanning fragment in the biogenesis of <i>Escherichia coli</i> K12 outer membrane protein PhoE," <i>Mol Gen Genet</i> , 216:144-148, 1989.
	C20	Boss <i>et al.</i> , "Assembly of functional antibodies from immunoglobulin heavy and light chains synthesised in <i>E. Coli</i> ," <i>Nucl. Acids Res.</i> , 12(9):3791-3807, 1984.
	C21	Breitling <i>et al.</i> , "A surface expression vector for antibody screening," <i>Gene</i> , 104:147-153, 1991.
	C22	Breyer and Sauer, "Mutational analysis of the fine specificity of binding of monoclonal antibody 51F to $\lambda$ repressor," <i>J. Biol. Chem.</i> , 264(22):13355-13360, 1989.
	C23	Brown, "Engineered iron oxide-adhesion mutants of the <i>Escherichia coli</i> phage $\lambda$ receptor," <i>Proc. Natl. Acad. Sci. USA</i> , 89:8651-8655, 1992.
	C24	Buckholz, "Yeast systems for the expression of heterologous gene products," <i>Curr. Opin. Biotechnol.</i> , 4(5):538-542, 1993.
	C25	Buell <i>et al.</i> , "Optimizing the expression in <i>E. coli</i> of a synthetic gene encoding somatomedin-C (IGF-I)," <i>Nucl. Acids Res.</i> , 13(6), 1985.
	C26	Burks <i>et al.</i> , "In vitro Scanning Saturation Mutagenesis of an Antibody Binding Pocket," <i>Proc. Natl. Acad. Sci.</i> , 94:412-417, 1997.
	C27	Cabilly <i>et al.</i> , "Generation of antibody activity from immunoglobulin polypeptide chains produced in <i>E. Coli</i> ," <i>Proc. Natl. Acad. Sci. USA</i> , 81:3273-3277, 1984.
	C28	Caton and Koprowski, "Influenza virus hemagglutinin-specific antibodies isolated from a combinatorial expression library are closely related to the immune response of the donor," <i>Proc. Natl. Acad. Sci. USA</i> , 87:6450-6454, 1990.
	C29	Chang <i>et al.</i> , "Phenotypic expression in <i>E. coli</i> of a DNA sequence coding for mouse dihydrofolate reductase," <i>Nature</i> , 275:617-624, 1978.
	C30	Chang <i>et al.</i> , "Membrane biogenesis: Cotranslational integration of the bacteriophage f1 coat protein into an <i>E. Coli</i> membrane fraction," <i>Proc. Natl. Sci. USA</i> , 76:1251-1255, 1979.

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1646

U.S. Patent Documents

See Page 1

Foreign Patent Documents

See Page 3

Other Art

See Page 3

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Exam. Init.	Ref. Des.	Citation
	C31	Charbit <i>et al.</i> , "Versatility of a vector for expressing foreign polypeptides at the surface of Gram-negative bacteria," <i>Gene</i> 70:181-189, 1988.
	C32	Charbit <i>et al.</i> , "Permissive sites and topology of an outer membrane protein with a reporter epitope," <i>J. Bact.</i> , 173(1):262-275, 1991.
	C33	Charles and Dougan, "Gene expression and the development of live enteric vaccines," <i>Trends in Biotechnology</i> , 8:117-121, 1990.
	C34	Chen <i>et al.</i> , "A quantitative immunoassay utilizing <i>E. coli</i> cells possessing surface-expressed single chain Fv molecules," <i>BioTech. Prog.</i> , 12:572-574, 1996.
	C35	Chiang <i>et al.</i> , "Direct cDNA cloning of the rearranged immunoglobulin variable region," <i>BioTechniques</i> , 7(4):360-366, 1989.
	C36	Chiswell and McCafferty, "Phage antibodies: will new 'coliclonal' antibodies replace monoclonal antibodies?", <i>Tibtech</i> , 10:80-84, 1992.
	C37	Clackson <i>et al.</i> , "Making antibody fragments using phage display libraries," <i>Nature</i> , 352:624-628, August 1991.
	C38	Colizzi <i>et al.</i> , "Analysis of Mycobacterium tuberculosis genome and production of a recombinant protein containing specific B and T cell antigenic determinants -- new approaches to second generation antituberculosis vaccines," <i>Z Erkr Atmungsorgane</i> , 172(1):40-52, 1989.
	C39	Cornelis <i>et al.</i> , "Development of new cloning vectors for the production of immunogenic outer membrane fusion proteins in <i>Escherichia coli</i> ," <i>Bio/Technology</i> , 14:203-208, 1996.
	C40	Cryz, "Live attenuated vaccines for human use," <i>Curr. Opin. BioTech.</i> , 3(3):298-302, 1992.
	C41	Danziger <i>et al.</i> , "Simultaneous gene amplification and gene detection using three PCR primers," <i>BioTechniques</i> , 14(3):370, 1993.
	C42	De Libero and Kaufmann, "Antigen-specific LYT-2 <sup>+</sup> cytolytic T lymphocytes from mice infected with the intracellular bacterium <i>Listeria Monocytogenes</i> ," <i>J. Immun.</i> , 137(8):2688-2694, 1986.
	C43	Denzin <i>et al.</i> , "Single-chain site-specific mutations of fluorescein-amino acid contact residues in high affinity monoclonal antibody 4-4-20," <i>J. Biol. Chem.</i> , 266(21):14095-14103, 1991.
	C44	Derbyshire <i>et al.</i> , "A simple and efficient procedure for saturation mutagenesis using mixed oligodeoxynucleotides," <i>Gene</i> , 46:145-152, 1986.

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Exam. Init.	Ref. Des.	Citation
	C45	Devlin <i>et al.</i> , "Random peptide libraries: A source of specific protein binding molecules," <i>Science</i> , 249:404-406, 1990.
	C46	Dougan <i>et al.</i> , "Live bacterial vaccines and their applications as carriers for foreign antigens," <i>Ad Vet Sci Compara Med</i> , 33:271-300, 1989.
	C47	Dunn, "Phage display of proteins," <i>Curr. Opin. Biotechnol.</i> , 7(5):547-553, 1996.
	C48	Eckart and Bussineaus, "Quality and authenticity of heterologous proteins synthesized in yeast," <i>Curr. Opin. BioTech.</i> , 7(5):525-530, 1996.
	C49	Ehrman <i>et al.</i> , "Genetic analysis of membrane protein topology by a sandwich gene fusion approach," <i>Proc Natl Acad Sci USA</i> , 87:7574-7578, 1990.
	C50	Filloux <i>et al.</i> , "Protein secretion in gram-negative bacteria: transport across the outer membrane involves common mechanisms in different bacteria," <i>EMBO J.</i> , 9(13):4323-4329, 1990.
	C51	Fischetti <i>et al.</i> , "Expression of foreign proteins on gram-positive commensal bacteria for mucosal vaccine delivery," <i>Curr. Opin. Biotechnol.</i> , 4(5):603-610, 1993.
	C52	Fischetti, "Gram-positive commensal bacteria deliver antigens to elicit mucosal and systemic immunity," <i>ASM News</i> 62:405-410, 1996.
	C53	Francisco and Georgiou, "The expression of recombinant proteins on the external surface of <i>Escherichia coli</i> . Biotechnological applications," <i>Ann. NY Acad. Sci.</i> , 745:372-382, 1994.
	C54	Francisco <i>et al.</i> , "Production and fluorescence-activated cell sorting of <i>Escherichia coli</i> expressing a functional antibody fragment on the external surface," <i>Proc. Natl. Acad. Sci. USA</i> , 90:10444-10448, 1993.
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	C56	Francisco <i>et al.</i> , "Transport and anchoring of $\beta$ -lactamase to the external surface of <i>Escherichia coli</i> , <i>Proc. Natl. Acad. Sci. USA</i> , 89:2713-2717, April 1992.
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JAN 03 2002

Page 8 of 19

Form PTO-1449 (modified)

List of Patents and Publications for Applicant's

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Atty. Docket No.

MXGN:005USC2/SLH

Serial No.

09/813,444

Applicant

Brent Iverson *et al.*

Filing Date:

March 20, 2001

Group:

1646

U.S. Patent Documents

See Page 1

Foreign Patent Documents

See Page 3

Other Art

See Page 3

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JAN 03 2002

Form PTO-1449 (modified)

List of Patents and Publications for Applicant's

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Atty. Docket No.

MXGN:005USC2/SLH

Serial No.

09/813,444

Applicant

Brent Iverson *et al.*

Filing Date:

March 20, 2001

Group:

1646

U.S. Patent Documents

See Page 1

Foreign Patent Documents

See Page 3

Other Art

See Page 3

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JAN 0 '3 2002

Page 10 of 19

Form PTO-1449 (modified)		Atty. Docket No. MXGN:005USC2/SLH	Serial No. 09/813,444
List of Patents and Publications for Applicant's  INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)		Applicant Brent Iverson <i>et al.</i>	
		Filing Date: March 20, 2001	Group: 1646
U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 3</i>	Other Art <i>See Page 3</i>	

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Form PTO-1449 (modified)

List of Patents and Publications for Applicant's

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Atty. Docket No.

MXGN:005USC2/SLH

Serial No.

09/813,444

Applicant

Brent Iverson *et al.*

Filing Date:

March 20, 2001

Group:

1646

U.S. Patent Documents

See Page 1

Foreign Patent Documents

See Page 3

Other Art

See Page 3

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

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Form PTO-1449 (modified)

List of Patents and Publications for Applicant's

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Atty. Docket No.

MXGN:005USC2/SLH

Serial No.

09/813,444

Applicant

Brent Iverson *et al.*

Filing Date:

March 20, 2001

Group:

1646

U.S. Patent Documents

See Page 1

Foreign Patent Documents

See Page 3

Other Art

See Page 3

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JAN 0 '3 2002

Form PTO-1449 (modified)

## List of Patents and Publications for Applicant's

## INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Atty. Docket No.

MXGN:005USC2/SLH

Serial No.

09/813,444

Applicant

Brent Iverson *et al.*

Filing Date:

March 20, 2001

Group:

1646

U.S. Patent Documents

See Page 1

Foreign Patent Documents

See Page 3

Other Art

See Page 3

## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

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Form PTO-1449 (modified)		Atty. Docket No. <b>MXGN:005USC2/SLH</b>	Serial No. <b>09/813,444</b>
List of Patents and Publications for Applicant's  INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)		Applicant <b>Brent Iverson <i>et al.</i></b>	
		Filing Date: <b>March 20, 2001</b>	Group: <b>1646</b>
U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 3</i>	Other Art <i>See Page 3</i>	

**Other Art (Including Author, Title, Date Pertinent Pages, Etc.)**

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Form PTO-1449 (modified)		Atty. Docket No. MXGN:005USC2/SLH	Serial No. 09/813,444
List of Patents and Publications for Applicant's  INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)		Applicant Brent Iverson <i>et al.</i>	
		Filing Date: March 20, 2001	Group: 1646
U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 3</i>	Other Art <i>See Page 3</i>	

### Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

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Form PTO-1449 (modified)		Atty. Docket No. MXGN:005USC2/SLH	Serial No. 09/813,444
List of Patents and Publications for Applicant's  INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)		Applicant Brent Iverson <i>et al.</i>	
		Filing Date: March 20, 2001	Group: 1646
U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 3</i>	Other Art <i>See Page 3</i>	

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U.S. Patent Documents See Page 1	Foreign Patent Documents See Page 3	Other Art See Page 3	

### Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

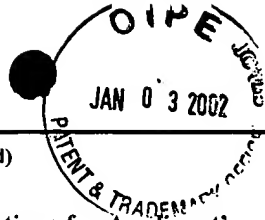
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MXGN:005USC2/SLH

Serial No.

09/813,444

Applicant

Brent Iverson *et al.*

Filing Date:

March 20, 2001

Group:

1646

U.S. Patent Documents

See Page 1

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See Page 3

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See Page 3

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	C192	Ward <i>et al.</i> , "Binding activities of a repertoire of single immunoglobulin variable domains secreted from <i>E. coli</i> ," <i>Nature</i> , 341:544-546, 1989.
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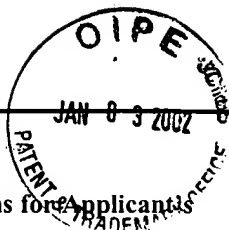
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March 20, 2001

Group:

1646

U.S. Patent Documents

*See Page 1*

Foreign Patent Documents

*See Page 3*

Other Art

*See Page 3*

## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C205	U.S. Patent Application Serial No. 08/447,402 filed May 23, 1995.

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